FEB 2 8 2001

510(k) Summary

K003762

Summary of Safety and Effectiveness for ALI 3D Tool Module for Medical Images

5.1 Demographic Information

5.1.1 Date Prepared

December 4, 2000

5.1.2 Submitter

A.L.I. Technologies Inc.
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5.1.3 Contact

Robert MacNeil P.Eng.
Manager, Quality and Regulatory Affairs

5.2 Device Name

5.2.1 Trade or Proprietary Name

ALI 3D Tool Module for Medical Images

5.2.2 Common Name

ALI 3D Tool Module for Medical Images

5.2.3 Classification Name

Picture Archiving and Communications System (per 21 CFR 892.2050).

5.3 Devices to which Substantial Equivalence is being Claimed

510(k) Number	Device Name	Manufacturer
K992654	Plug 'N View 3D, Version 1.0	Voxar Limited
K002519	Vitrea 2, Version 2.1	Vital Images Inc.

5.4 Device Description

5.4.1 Function

The ALI 3D Tool Module for Medical Images is an accessory plug-in program for the ALI UltraPACS Picture Archiving and Communications System workstation software (K925965/A). It reads DICOM 3.0 format 3D medical image data sets stored by the ALI UltraPACS system and displays 3D image constructions of these data sets through various user selectable industry standard rendering methods and algorithms.

Clinical users can also spatially manipulate, process to highlight features, areas and volumes of interest, measure distances, areas, and volumes in the 3D image constructions, store a 2D picture of a 3D image in DICOM 3.0 format, and store one or more slices of the 3D image dataset in DICOM 3.0 format.

The ALI 3D Tool Module for Medical Images requires ALI UltraPACS workstation software, which runs on commercially available IBM PC compatible computers and hardware components with the Microsoft Windows NT 4.0 operating systems.

5.4.2 Scientific Concept

The ALI 3D Tool Module for Medical Images uses commercially available, industry standard methods and algorithms for rendering 3D images, and industry standard methods and algorithms for measuring distances, areas, and volumes of interest.

5.4.3 Significant Physical and Performance Characteristics

Medical Image Modalities
• All DICOM 3.0 recognized modalities where datasets are comprised of parallel, 2D images with known inter-image spacing.
Multi-Planar Reformatting (MPR)
• 3 quadrants view (coronal + sagittal + transverse planes)
• Translate 3 planes
• Rotate all 3 views about all 3 axes
• Display lines of intersection between planes
• Adjust location and orientation of planes via movement of the intersection lines in all 3 views
• Rotate current slice
• Tip current slice
• Quickslice
• Link/unlink for window-level/pan/zoom
• Patient Orientation labels
• Adjustable text on labels (full text for label or abbreviation of label)
• Borders to highlight "current" plane
• Render greyscale with artificial colors
• Adjustable window-level
• Reset window-level/pan/zoom/orientation
• Undo window-level/pan/zoom/orientation
Maximum Intensity Projection (MIP) Minimum Intensity Projection (mIP) and Volume Rendering (VR)
• Show MIP / mIP / VR and 3 quadrant views concurrently
• Rotate
• Adjustable wire-frame clipping in rendered view
• Adjustable clipping boxes in 3 quadrant views
• Window level protocols
• Pan
• Zoom
• Render greyscale with artificial colors
• Adjustable window-level
• Reset Rotation/Clipping/Brightness/Opacity
• Undo Rotation/Clipping/Brightness/Opacity
Feedback View (FV)
• Wire frame rotated to current viewpoint
• Texture mapped MPR plane
• Ability to translate texture mapped MPR plane

• Ability to tip/rotate texture mapped MPR plane
Image Processing (IP)
• Rotation
• Pan
• Zoom
• Opacity
• Window Level (Brightness)
• Light location in rendered views
• Clipping
• Color renderings
• Manual color painting of the renderings
Measurements
• Distance
• Area
• Volume
Image Layout
• Single quadrant/3 quadrant toggle (i.e. zoom single quadrant)
Image Storage
• Add 3D rendered image to current study
• Add one or more slices to current study

5.5 Statement of Intended Use

The ALI 3D Tool Module for Medical Images is an accessory plug-in to the ALI UltraPACS Picture Archiving and Communication System workstation software. ALI 3D Tool Module for Medical Images is intended to provide the following capabilities:

1. visualization of 3D image constructions of previously stored DICOM 3.0 format 3D image datasets through various industry standard rendering methods and algorithms;
2. spatial manipulation of the 3D images;
3. processing of the 3D images to highlight features, areas and volumes of interest;
4. measurement of distances, areas and volumes in the 3D images;
5. storage of a 2D picture of a 3D image in DICOM 3.0 format;
6. storage of one or more slices of the 3D image dataset in DICOM 3.0 format.

5.6 Comparison of Technological Characteristics

The ALI 3D Tool for Medical Images is substantially equivalent to the Voxar Limited *Plug 'N View 3D, Version 1.0* (K992654) for non-measurement features and to the Vital Images Inc. *Vitrea 2, Version 2.1* (K002519) for measurement features.

Feature	**ALI 3D Tool for Medical Images**	**Voxar Plug 'N View 3D, Version 1.0**
Type of Software Program	Plug in module for ALI UltraPACS workstations	Stand alone application program
Software platform required	Window NT 4.0, and ALI UltraPACS	Windows 95/98/NT

	workstation software	
Medical Image Modalities		
All DICOM 3.0 recognized modalities where datasets are comprised of parallel, 2D images with known inter-image spacing.	Yes	Yes
Multi-Planar Reformatting (MPR)		
3 quadrants view (coronal + sagittal + transverse planes)	Yes	Yes
Translate 3 planes	Yes	Yes
Rotate all 3 views about all 3 axes	Yes	No
Display lines of intersection between planes	Yes	Yes
Adjust location and orientation of planes via movement of the intersection lines in all 3 views	Yes	No
Rotate current slice	Yes	Limited (just 90 degree increments)
Tip current slice	Yes	No
Quickslice	Yes	No (only orthogonal slices)
Link/unlink for window-level/pan/zoom	Yes	No
Patient Orientation labels	Yes	Yes
Adjustable text on labels	Yes (full text for label or abbreviation of label)	Yes
Borders to highlight "current" plane	Yes	Yes
Tile Mode	Yes (provided as part of ALI UltraPACS workstation software)	Yes
Render greyscale with artificial colors	Yes	No
Adjustable window-level	Yes	Yes
Reset window-level/pan/zoom/orientation	Yes	Yes
Undo window-level/pan/zoom/orientation	Yes	Yes
Maximum Intensity Projection (MIP) Minimum Intensity Projection (mIP) and Volume Rendering (VR)		
Show MIP / mIP / VR and 3 quadrant views concurrently	Yes	Yes
Rotate	Yes	Yes
Adjustable wire-frame clipping in rendered view	Yes	Yes
Adjustable clipping boxes in 3 quadrant views	Yes	Yes
Window level protocols	Yes	Yes
Snap to nearest orthogonal viewpoint	No (but can be reset to orthogonal viewpoints)	Yes
Reverse video (invert window-level)	No	Yes
Pan	Yes	Yes
Zoom	Yes	Yes
Render greyscale with artificial colors	Yes	No
Adjustable window-level	Yes	Yes

Reset Rotation/Clipping/Brightness/Opacity	Yes	Limited (for rotation only)
Undo Rotation/Clipping/Brightness/Opacity	Yes	Yes
Feedback View (FV)		
Wire frame rotated to current viewpoint	Yes	Limited (small view, abbreviated patient orientation, fixed choices for rotation increments)
Texture mapped MPR plane	Yes	No
Ability to translate texture mapped MPR plane	Yes	No
Ability to tip/rotate texture mapped MPR plane	Yes	No
Image Processing (IP)		
Rotation	Yes	Yes
Pan	Yes	Yes
Zoom	Yes	Yes
Flip according to patient orientation	No	Yes
Opacity	Yes	Yes
Window-Level (Brightness-Contrast)	Yes	Yes
Light location in rendered views	Yes	Yes
Orthogonal clipping	Yes	Yes
Sculpting (clipping in non-orthogonal planes)	No	Yes
Color renderings	Yes	No
Manual color painting of the renderings	Yes	No
Image Layout		
Single quadrant/3 quadrant toggle (i.e. zoom single quadrant)	Yes	Yes
Image Storage		
Add 3D rendered image to current study	Yes	No
Add one or more slices to current study	Yes	No
Hardcopy Generation		
Print to DICOM and non-DICOM printers	Yes (printing handled by ALI UltraPACS workstation software)	Yes
Measurements		
Distance	Yes	No
Area	Yes	No
Volume	Yes	No

Feature	**ALI 3D Tool for Medical Images**	**Vital Images Vitrea 2, Version 2.1**
Type of Software Program	Plug in module for ALI UltraPACS workstations	Stand alone application program
Hardware / Software platform required	Pentium III,	Windows NT

	Window NT 4.0, ALI UltraPACS workstation	
Medical Image Modalities		
All DICOM 3.0 recognized modalities where datasets are comprised of parallel, 2D images with known inter-image spacing.	Yes	Yes
Measurements		
Distance	Yes	Yes
Area	Yes	Yes
Volume	Yes	Yes

For non-measurement features, the ALI 3D Tool Module for Medical Images is basically a superset of features of the Voxar Limited *Plug 'N View 3D Version 1.0*. For the measurement features, ALI 3D Tool Module for Medical Images is the same as the Vital Images *Vitrea 2 Version 2.1.*

In conclusion, ALI 3D Tool Module for Medical Images is substantially equivalent to the Voxar Limited *Plug 'N View 3D Version 1.0* for non-measurement features and the Vital Images *Vitrea 2 Version 2.1* for measurement features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2001

Mr. Robert MacNeil, P. Eng.
Manager, Quality and Regulatory Affairs
A.L.I. Technologies, Inc.
#130-10711 Cambie Road
Richmond, BC
Canada V6X 3G5

Re: K003762
ALI 3D Tool Module for Medical Images
Dated: December 4, 2000
Received: December 6, 2000
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. MacNeil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003761

Device Name: ALI 3D Tool Module for Medical Images

Indications For Use:

ALI 3D Tool Module for Medical Images is indicated for use with ALI UltraPACS Picture Archive and Communications Systems workstations where physicians, medical imaging specialists, and medical imaging operators desire:

1. visualizing 3D image constructions of previously stored DICOM 3.0 format 3D image datasets through various industry standard rendering methods and algorithms;
2. spatially manipulating the 3D images;
3. processing the 3D images to highlight features, areas and volumes of interest;
4. measuring distances, areas and volumes in the 3D images;
5. storing a 2D picture of a 3D image in DICOM 3.0 format;
6. storing one or more slices of the 3D image dataset in DICOM 3.0 format.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003761